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The National Strategic Stockpile: Will it Really Protect the Nation against Bioterrorism?

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This paper is submitted in satisfaction of the course requirement.

Abstract:

This paper assesses one of the key components of the nation's defense against bioterrorism—the National Strategic Stockpile. The Stockpile was created by the Bioterrorism Act of 2002 and Project Bioshield in 2004, with a mandate to procure sufficient vaccines, medicines and other products to avert or contain a public health crisis in the event of a bioterrorist attack. Currently, the Stockpile lacks critical countermeasures and next generation vaccines because they have not yet been developed. Congress has attempted to provide the conditions necessary for the private sector to create these products for the National Stockpile, but Congress's efforts have largely failed thus far. This paper will examine both aspects of the National Strategic Stockpile: first it will examine the legislation providing for the National Strategic Stockpile and the strategy to provide the private market with incentives to develop priority countermeasures. Second, this paper will then analyze the strengths and weaknesses of the legislation and offer recommendations for future governmental actions to ensure the successful build-up of a robust National Strategic Stockpile.

I. Introduction: The Threat

September 11, 2001 opened the eyes of the American public to the threat of terrorism within its own borders. Within a week of the World Trade Center attacks, an even more specific form of terrorism grabbed the nation's headlines: bioterrorism.¹ Anthrax-laced letters sent to Senators and members of the press

¹Many were aware of the threat prior to September 11th, but they did not capture the attention of the public. See, e.g.,

resulted in five deaths, set off a flurry of F.B.I. activity, and kept Americans glued to the news outlets.² While the sender of those letters remains a mystery,³ the potential threat of bioterrorism does not: the public is now acutely aware of the dangers presented by a bioterrorist attack on the nation's food,⁴ water,⁵ or drug⁶ supply. In response to this post-September 2001 reality, Congress quickly passed legislation designed to meet the threat of bioterrorism.

This paper will analyze one prominent component of Congress's legislative response⁷—the creation of a strategic national stockpile of drugs, vaccines and other countermeasures critical to identifying, diagnosing, and treating victims in the event of bioterrorism. Part II will provide an overview of the relevant provisions

Heather A. Dagen, Comment, *Bioterrorism: Perfectly Legal*, 49 CATH. U.L. REV. 535, FN 1-2 (2000), for citations to the literature discussing the threat of bioterrorism pre-September 11; Donald Wette et al., *Hospital Preparedness for victims of Chemical or Biological Terrorism*, AMER. J. OF PUBLIC HEALTH, May 2001, at 710 (study finds that 4 North-east hospitals seriously unprepared for biological attacks and out of sync with national preparedness efforts); *Bioterrorism: Our Frontline Response, Evaluating U.S. Public Health and Medical Readiness: Hearings on P.L 106-505 Before the Subcomm. on Public Health of the Senate Committee on Health, Education, Labor, and Pensions*, 106th Cong. (1999).

²Philip Shenon, *A National Challenge: Discovery on Anthrax; Suspicious Letter to a 2nd Senator*, N.Y. TIMES, Nov. 17, 2001, at A1 (Senator Leahy receives anthrax-laced letter, after Senator Daschle, NBC News and the New York Post had already received similar letters); William J. Broad and David Johnston, *Anthrax sent through mail gained potency by the letter*, N.Y. TIMES, May 7, 2002, at A1.

³Scott Shane, *In a 4-Year Anthrax Hunt, F.B.I. Finds Itself stymied, and sued*, N.Y. TIMES, September 17, 2005, at A1 (F.B.I failed to identify the culprit of the 2001 anthrax letters; the F.B.I. did target persons of interest such as Dr. Steven J. Hatfill, but never charged anyone with the crimes).

⁴See Caroline Smith Dewaal, *Rising Imports, Bioterrorism and the Food Supply*, 59 FOOD DRUG L.J. 433, 436 (Secretary of HHS, Tommy Thompson testified before Congress in 2002 that "[Food safety] is one area in which we must be more vigilant, because disease-causing agents can easily be spread through the food supply (citing S.G. Stolberg & J. Miller, *Many Worry That Nation Is Still Highly Vulnerable to Germ Attack*, N.Y. TIMES, Sept. 9, 2002, at 16)). The general need to bolster the nation's food security against intentional and non-intentional biological agents has been discussed elsewhere, see, e.g., Michael R. Taylor, *Lead or React? A game plan for modernizing the food safety system in the U.S.*, 59 FOOD DRUG L.J. 399 (2004)(although the food supply is not in crisis, there is a need to modernize the system to address the threat of food-borne biological illness); Lisa Lovett, Note and Comment: *Food for Thought: Consistent Protocol could strengthen food supply security measures*, 10 TEX. WESLEYAN L. REV. 465 (2004).

⁵See U.S. Environmental Protection Agency, *Water Security*, available at <http://cfpub.epa.gov/safewater/watersecurity/index.cfm> (last visited on Feb. 8, 2006), for resources and information relating to the threat posed to the U.S. water supply by bioterrorism. See also, Victoria Sutton, *Environment and Public Health in a Time of Plague*, 30 AM. J. L. AND MED. 217 (2004)(discussing the federal environmental law in place to address the threat of a bioterrorist attack on the water supply).

⁶Congress responded in part to this threat in Title III, §321-322 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (requiring annual registration of foreign manufacturers; shipping information; drug and device information).

⁷This paper will assume the reader is familiar with the seriousness and potential large-scale impact of bioterrorism and will therefore focus on Congress's response alone. But for general background information on the nature and seriousness of potential bioterrorism, see Gregory Koblentz, *Responding to the Bioweapons Threat*, p. 84, INTERNATIONAL SECURITY (Winter 2004)(explores the security implications of pathogens used as weapons); David Koplow, *That Wonderful Year: Smallpox, Genetic Engineering, and Bioterrorism*, 62 MD. L. REV. 417 (2003)(discussing the serious nature of unconventional bioterrorism in the context of smallpox and genetic engineering and their incorporation into the military strategy of the Soviet Union and the United States); Barry Kellman, *Biological Terrorism: Legal Measures for Preventing Catastrophe*, 24 HARV. J.L. & PUB. POL'Y 417 (2001)(Part I explains the threat of bioterrorism and how such attacks would occur).

requiring this national stockpile, particularly within the Bioterrorism Act of 2002⁸ and Project BioShield Act of 2004,⁹ and flush out Congressional rationales for adopting these specific provisions. Part III will analyze the strengths and weaknesses of these provisions, evaluate the stockpile-related legislation currently pending in Congress, and offer recommendations for future Congressional action.

II. The Legislation: Provisions and background

Focus upon a national stockpile of vaccines and other countermeasures gradually increased after the events of September 2001. As the following discussion will demonstrate, Congress originally placed modest emphasis on the national stockpile provisions in the Bioterrorism Act of 2002, but then placed significant emphasis on it with the passage of Project Bioshield in 2004.

A. The Bioterrorism Act of 2002¹⁰

The Bioterrorism Act of 2002 [hereinafter Bioterrorism Act] represented Congress's first attempt to organize a coherent national bioterrorism-security strategy. Proving that it can achieve quick results if so desired, Congress passed the Bioterrorism Act within eight months of being introduced with bi-partisan support in each respective chamber.¹¹ Three broad elements define Congress's approach in 2002:¹² first, coordinate a

⁸Officially titled "Public Health Security and Bioterrorism Preparedness and Response Act of 2002," Pub. L. No. 107-188, 116 Stat. 594.

⁹Pub. L. No. 108-276, 118 Stat. 835 (2004).

¹⁰Pub. L. No. 107-188, 116 Stat. 594 (2002).

¹¹Senators Frist and Kennedy introduced the Senate version on November 15, 2001 (S. 1765); Representatives Tauzin (R-LA) and Dingell (D-MI) introduced the House version on December 11, 2001 (H.R. 3448). See Stephen Redhead, Donna U. Vogt and Mary E. Tiemann, *Bioterrorism: Legislation to improve Public Health Preparedness and Response Capacity*, CRS REPORT RL 31263, Jan. 31, 2002, for a side by side analysis of the two bills.

¹²For an analysis of the first Title I-II, see Ryan Kemper, Note: *Responding to Bioterrorism: An analysis of Titles I and II of the Public Health Security and Bioterrorism Preparedness and Reponse Act of 2002*, 83 WASH. U. L. Q. 385 (2005). See also Covington & Burling report, *The Food Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, May 31, 2002; Covington & Burling report, *The Drug Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, June 12, 2002.

coherent national response strategy in the event of bioterrorist attacks.¹³ Second, regulate and track dangerous biological agents and toxins circulating within the United States.¹⁴ Third, enhance security of the nation's critical resources, including the food, drug and water supplies.¹⁵ While all three elements provide fodder for much academic and policy debate,¹⁶ the stockpile provisions fall under the first element of coordinating a national response strategy of preparedness (Title I of the Bioterrorism Act) and will be the focus of this paper.

Creating a coherent strategy of national preparedness presented Congress with a deep and enduring challenge even before September 11. Warnings of the lack of coordination between local, state and federal agencies abounded before the World Center attacks; moreover, numerous experts and interested parties exposed the general lack of preparedness prevalent among hospitals and other front line responders.¹⁷ With this in mind, Congress used the Title I of the Bioterrorism Act to lay out a broad and multifaceted national strategy to respond to a bioterrorist attack. The first prong of this strategy concentrated on coordinating local, state, and federal agencies and addressing the disconnect between and among the levels of government.¹⁸ A second prong focused on assisting state and local hospitals in preparing for bioterrorism or other related health

¹³Title I, The Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

¹⁴Title II, The Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

¹⁵Title III-IV, The Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

¹⁶Much has been written on the need for security of our food and water supplies in particular. See *supra* note 4 and 5. See also, e.g., Matthew Boyle, *A Recipe for Disaster*, FORTUNE, p 59-60, November 14, 2005 (discussing how the National Center for Food Protection and Defense is trying to bolster food security, and notes a recent Stanford study that found a small amount of botulinum toxin poured into a milk tanker truck could cause hundreds of thousands of deaths); Mark Wheelis et al., *Biological Attack on Agriculture: Low-Tech, High-Impact Bioterrorism*, BIOSCIENCE, p 569, July 2002 (bioterrorist attacks on agriculture require little expertise and U.S. agriculture is vulnerable to such attacks); *Drinking-Water Security*, JOURNAL OF ENVIRONMENTAL HEALTH, p. 41, Sept. 2003 (since the Sept. 11, the EPA has contributed to increased security of the nation's water supply).

¹⁷For pre-Sept 11th warnings, see generally *Bioterrorism: Our Frontline Response, Evaluating U.S. Public Health and Medical Readiness: Hearings on P.L 106-505 Before the Subcomm. on Public Health of the Senate Committee on Health, Education, Labor, and Pensions*, 106th Cong. 21 (1999). For a post-Sept 11th evaluation of local preparedness, see Robin J. Strongin and C. Stephen Redhead, *Bioterrorism: Summary of a CRS/National Health Policy Forum Seminar on Federal, State, and Local Public Health Preparedness*, CRS REPORT RL 31225, Dec. 21, 2002.

¹⁸Title I, Subtitle A, § 101-11, The Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594. See generally, Victoria Sutton, *Biodefense—Who's in Charge?*, 13 HEALTH MATRIX 117 (Winter 2003)(discussing the disorganized structure of federal agencies relating to biodefense and the need to create a coordinated national system of public surveillance and reporting); *Hearing on Federal Efforts to Coordinate and Prepare the U.S. for Bioterrorism—Are they Ready? before the House Committee on Governmental Affairs*, S. Hrg. 107-213, Oct. 17, 2001 (testimony on need to coordinate federal response and capacity to assist local and state authorities in the event of bioterrorism).

crises.¹⁹ The third prong provided for the creation of a strategic national stockpile and the development of priority countermeasures.²⁰

Two aspects of the national stockpile provisions in the Bioterrorism Act stand out as significant. First, the national stockpile provisions constitute only one of many priorities within the Bioterrorism Act, and even within Title I itself. Arguably, Congress's greater emphasis regarding a national response and preparedness strategy lay in the coordination of local, state, and federal actors and bulking up the resources and preparedness at the local and state level.²¹ Second, there are two distinct goals of the section: to compile the stockpile (and \$640 million was authorized for fiscal year 2002 towards this end)²² and to ensure the development and expedited approval of priority countermeasures intended to make up the national stockpile.²³ To meet the latter goal, the Bioterrorism Act provides for "fast track" designation under the Food, Drug and Cosmetic Act for any priority countermeasures so designated by the Secretary of HHS and the FDA Commissioner, allows measures to receive fast track status even if effectiveness is based on animal studies,²⁴ and provides

¹⁹§ 131, The Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594. States received over \$1 billion for preparedness plans in 2002. See HHS Press Release, *Bioterrorism Preparedness Grants*, June 6, 2002.

²⁰Title I, Subtitle B, § 121-127, The Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

²¹A quick count of the hearings related to coordination issues as opposed to vaccines and the stockpile demonstrate this—approximately eleven hearings were held on coordination needs between local and state governments versus five held on vaccine R & D. See *Legislative History of P.L. 107-188*, 107 CIS Legis. Hist. P.L. 188, Hearings. Hearings held on research and development of vaccines and other protections included: House Committee on Government Reform, *Quickening the Pace of Research in Protecting Against Anthrax and Other Biological Terrorist Agents: A Look at Toxin Interference*, Feb. 28, 2002; Hearing before the Subcom on National Security, Veterans Affairs and International Relations of the House Committee on Government Reform, *Biological Warfare Defense Vaccine Research and Development Program*, Oct. 23, 2001. The emphasis on coordination issues is also explained by the fact that pre-September 11, the pervasive sentiment seemed to view the local and state governments as the primary actors in any bioterrorist attack, while federal actors assisted. See, e.g., Prepared Statement of Mr. Charles L. Cragin (Principal Undersecretary of Defense), *Research and Development to support domestic emergency preparedness for Response to Threats of Terrorist use of Weapons of Mass Destruction before the House Armed Services Committee*, March 11, 1999.

²²§121, Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594. ("The Secretary of Health and Human Services (referred to in this section as the Secretary), in coordination with the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.")

²³§ 122-125, The Bioterrorism Act of 2002.

²⁴§ 122, The Bioterrorism Act of 2002; see Gail Javitt, *Drugs and Vaccines for the Common Defense: Refining FDA Regulation to Promote the Availability of Products to Counter Biological Attacks*, 19 J. CONTEMP. HEALTH L. & POL'Y 37, 62-65 (2002)(explaining FDA rule regarding animal trials as acceptable evidentiary basis for countermeasures to bioterrorism).

priority funding for research institutions working on the development of priority countermeasures.²⁵ In short, while Congress required for the stockpile, the stockpile remained an uncertain project. Numerous other issues occupied the attention of Congress and the creation of a stockpile remained dependent in large part on the development of countermeasures and vaccines that could be stockpiled.

B.

Project Bioshield 2004²⁶

While the stockpile and development of countermeasures provisions represented only one of many priorities in the Bioterrorism Act of 2002, Project Bioshield focused solely on these issues. Introducing Project Bioshield in his 2003 State of the Union speech, President Bush heralded: “[a] major research and production effort to guard our people against bioterrorism, called Project Bioshield. The budget I send you will propose almost \$6 billion to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague. We must assume that our enemies would use these diseases as weapons, and we must act before the dangers are upon us.”²⁷ Towards this end, Project Bioshield honed in on the need to further develop a comprehensive strategy to develop and procure *modern* vaccines and drugs capable of protecting against future bioterrorist attacks and pledged \$5.6 billion for a ten year special reserve fund to meet this goal.²⁸ Indeed, while treatment for many naturally-occurring diseases progressed rapidly in recent decades, treatment for bioterrorism—such as the smallpox vaccine—have progressed very little.²⁹

²⁵§125, The Bioterrorism Act of 2002.

²⁷White House Press Release, *President George W. Bush State of the Union*, January 28, 2003, full text available at <http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html> (last visited February 18, 2003).

²⁸See White House Press Release, *President Details Project Bioshield*, Feb. 3, 2003, available at <http://www.whitehouse.gov/news/releases/2003/02/20030203.html> (last visited on February 18, 2006).

²⁹See id; See also Prepared statement of Tommy G. Thompson, *Hearing before the House Energy and Commerce Subcommittee on Health and Committee on Homeland Security Subcommittee on Emergency Preparedness and Response*, March 27, 2003.

Project Bioshield entails three main components. All three components seek to prepare the nation for chemical, biological, radiological and nuclear (CBRN) attacks. A component significant for the purposes of this paper is found in the sections transferring the stockpile provisions from the Bioterrorism Act of 2002 to Project Bioshield.³⁰ Thus, the directive to maintain a national strategic stockpile now arises from Project Bioshield. In addition, Project Bioshield expands on this directive by instructing the HHS Secretary, in cooperation with the Homeland Security Secretary, to identify countermeasures appropriate to the nation's security but not yet available for procurement from the private sector or is available only for alternative uses. Once identified, the Secretaries should submit for Presidential approval proposals to develop and procure such countermeasures from the private sector with funds from the special reserve fund.³¹ Production and delivery of countermeasures so targeted must be feasible within eight years of the original contract for procurement.³² To facilitate such procurements, Project Bioshield authorizes a permanent funding source for the Secretary to utilize when procuring private sector vaccines, drugs and treatments.³³ In short, Project Bioshield authorizes HHS and DHS to actively identify, pursue and encourage the private sector to develop much needed vaccines and countermeasures critical to a successful national strategic stockpile.

Second, Project Bioshield seeks to spur government "countermeasure research and development." Thus, Project Bioshield expands on the cursory authority granted under the Bioterrorism Act to the HHS Secretary to take into account contributions made to bioterrorism-related goals when awarding grants, contracts or other funding to researchers.³⁴ Specifically, Project Bioshield grants the HHS Secretary and NIH Direc-

³⁰Sec. 3(a)(1), Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835 (2004) ("Transfer of program.—Section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (116 Stat. 611; 42 U.S.C. 300hh-12) is transferred from such Act to the Public Health Service Act, is redesignated as section 319F-2, and is inserted after section 319F-1 of the Public Health Service Act (as added by section 2 of this Act)").

³¹Sec. 3(c), Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835 (2004).

³²Sec. 3(c)(5)(A)(ii), Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835 (2004).

³³Sec. 3(f), Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835 (2004).

³⁴§125, "Accelerated Countermeasure Research and Development," The Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

tor authority to expedite procurement of cutting edge products and services necessary to facilitate research and development, which includes the power to make procurements in non-competitive settings where necessary³⁵; to expedite peer review procedures where necessary³⁶; and to streamline the process to contract out for experts and consultants necessary to accelerate research and development.³⁷ In direct contrast to the Bioterrorism Act of 2002, Project Bioshield provides the Secretary with authority to proactively pursue and encourage government research and development of priority countermeasures.

Project Bioshield's third and final main component permits the Secretary to introduce non-FDA approved drugs, devices, or biological products into interstate commerce in the event of an actual or potential emergency.³⁸ The statute authorizes the Secretary of Defense, Secretary of Homeland Security, and/or the Secretary of HHS to determine that an emergency or potential emergency sufficient to trigger these provisions exists.³⁹ Underscoring the seriousness of this scenario, Project Bioshield regulates every aspect of an emergency situation, including the conditions of authorization, the duration of an emergency, and the termination of an emergency.⁴⁰

In sum, Project Bioshield expands upon the Bioterrorism Act of 2002 and attempts to create a comprehensive and focused strategy to develop a modernized national strategic stockpile and arsenal of effective bioterrorism countermeasures. The following analysis will focus specifically on the first component of Project Bioshield discussed above that authorizes the government to aggressively identify and procure priority countermeasures

³⁵Sec. 2(b), Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835. Rep. Thomas Davis, *Project Bioshield: Contracting for the Health and Security of the American Public before the House Government Reform Committee*, April 4, 2003.

³⁶Sec. 2(c), Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835.

³⁷Up to thirty experts or consultants may be hired under this section. § 2(d), Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835 (2004).

³⁸Sec. 4, "Authorization for Medical Products for use in Emergency", Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835 (2004).

³⁹Sec. 4(b), Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835 (2004).

⁴⁰See generally, Sec. 4, Project Bioshield, Pub. L. No. 108-276, 118 Stat. 835 (2004).

from the private sector for the national strategic stockpile.

Part III. Analysis of the current provisions and guidance for future legislation

In analyzing Congress's national strategic stockpile provisions, this section will focus on three main issues: First, what is the current state of the national stockpile? Second, what are the strengths and weaknesses of the provisions aimed at fostering private sector research and development within the Bioterrorism Act and Project Bioshield? Third, what actions must Congress take to ensure a successful national stockpile and development of priority countermeasures?

A.

Current State of National Stockpile as it relates to Bioterrorism

As laid out already, the Bioterrorism Act and Project Bioshield require the creation of a national strategic stockpile:

[the Secretary] shall maintain a **stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies**. . . . to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.⁴¹

According to the HHS Strategic National Stockpile website, the Stockpile now contains large supplies of medicines and medical supplies, which states will receive within 12 hours of a determination by the federal government that a disaster exists and requires the Stockpile's resources.⁴² The exact contents of the stockpile

⁴²Department of Health and Human Services, Center for Disease Control and Prevention, *Strategic National Stockpile*,

remain classified for at least one obvious reason: full disclosure could harm the nation's security by giving potential terrorists information that would allow them to more effectively plot a deadly attack. Instead, the website broadly states that terrorism, earthquakes or flu outbreaks could trigger use of the strategic national stockpile.⁴³

Despite the classified nature of the strategic national stockpile, recent reports offer a relatively informative snapshot of the stockpile's current contents. Unfortunately, the picture leaves much to be desired. To begin, the stockpile contains only two of fifty-seven critical countermeasures as identified by the Department of Defense.⁴⁴ Such countermeasures refer to diagnostics, drugs and vaccines necessary to respond to bioterrorism.⁴⁵ Moreover, while the stockpile does include enough smallpox vaccines to vaccinate the whole country in an emergency,⁴⁶ the vaccines currently stockpiled are essentially the same vaccines used in the 1960s.⁴⁷ With the huge advancements made in science, technology and medical research over the last four decades, such stagnation in the modernization of smallpox vaccines seems worrisome at best. Similar concerns apply to the anthrax vaccines currently stockpiled: the anthrax vaccine presently stockpiled was licensed in 1970.⁴⁸

available at <http://www.bt.cdc.gov/stockpile/#means> (last visited on February 21, 2006).

⁴³*Id.*

⁴⁴Mark Kaufman, *Bioterrorism Response Hampered by Problem of Profit*, WASHINGTON POST, p A5, Aug. 7, 2005 (in 2000, the DOD reported that the US had only 1 of 57 countermeasures. Five years resulted in the creation of only one more critical countermeasure).

⁴⁵*Creating a BioDefense Industry: BioShield II: Hearing before the Senate Judiciary and Senate HELP Committees*, Oct 6, 2004 (Testimony by Senator Joe Lieberman, D-CT) (“[in 2000, the DOD] projected that we’d have twenty of the 57 within five years and 34 within 20 years. But, four years later, we have only two of the 57 countermeasures. . . At this rate of development, we will not have 20 countermeasures available until 2076 and we will not have 34 until 2132. And this list does not even include antibiotic resistant pathogens, hybrid pathogens, genetically modified pathogens, and a host of other exotic pathogens); cf. *Drug Problem: Biodefense*, ECONOMIST, April 24, 2004 (estimating 100 new diagnostics, vaccines and treatments are needed, which could take at least 5-10 years and \$50 billion).

⁴⁶*Furthering Public Health Security: Project BioShield: Hearing before the Subcommittee on Health, House Energy and Commerce Committee and the Subcommittee on Emergency Preparedness and Response, House Select Homeland Security Committee*, 108th Cong. (Mar. 27, 2003)(testimony by Dr. James Baker, a physician who is the Ruth Dow Doan Professor of Internal Medicine and Director of the Center for Biologic Nanotechnology at the University of Michigan).

⁴⁷See White House Press Release, *President Details Project Bioshield*, Feb. 3, 2003, available at <http://www.whitehouse.gov/news/releases/2003/02/20030203.html> (last visited on February 18, 2006).

⁴⁸*One Year Later: Evaluating the Effectiveness of Project BioShield: A Hearing before the House Committee on Government Reform*, 109th Cong. (July 14, 2005)(comments by US Rep Henry Waxman (D-CA)(criticizing the use of BioShield’s limited funds to buy such outdated vaccines).

Worse yet, the stockpile contains only five million anthrax vaccines doses—enough for only two percent of the population at best.⁴⁹

Determining what exists in the national stockpile alongside the anthrax and smallpox vaccines is more imprecise. According to testimony by the Assistant Secretary for Public Health, the stockpile contains countermeasures necessary to protect and treat “millions of Americans” in the event of an anthrax, plague or tularemia.⁵⁰ Also stockpiled are countermeasures such as Prussian Blue and diethylenetriaminepentaacetate (DTPA) that can address the effects of radiation exposure, and potassium iodide, which can protect the thyroid from some effects of radioactive iodide.⁵¹ Still, specifics as to how many scenarios such countermeasures could respond to—that is, how versatile or far-reaching in treatment the countermeasures are—and exactly how many Americans could be treated with the current inventory remain uncertain.

To be sure, federal authorities have plans to expand the national stockpile in the near future. Health and Human Services has begun the acquisition process for botulinum toxin, anthrax therapeutics, and the next generation of smallpox vaccine.⁵² In addition, HHS awarded a \$877 million contract to a small biotechnology firm, VaxGen, for the next generation anthrax vaccine.⁵³ While these steps are important, they represent only the first of many steps necessary to place the nation on the path towards a robust stockpile and strong preparedness to avert a public health crisis in the event of bioterrorism.

⁴⁹ *Id.*

⁵⁰ *One Year Later: Evaluating the Effectiveness of Project BioShield: A Hearing before the House Committee on Government Reform*, 109th Cong. (July 14, 2005) (statement of Stewart Simonson, Assistant Secretary, Public Health Emergency).

⁵¹ *Id.*

⁵² *One Year Later: Evaluating the Effectiveness of Project BioShield: A Hearing before the House Committee on Government Reform*, 109th Cong. (July 14, 2005) (statement by Dr. John Vitko, Director, Biological Countermeasures Portfolio, Science, and Technology Directorate, U.S. Department of Homeland Security).

⁵³ Richard Fisher, *Lights, Camera, Action: Project Bioshield*, NEW SCIENTIST, p 54, June 4, 2005.

B.

Strengths and Weaknesses of Congressional Stockpile and Countermeasures provisions

1. *Strengths*

Three main strengths characterize the national stockpile and countermeasure provisions in the Bioterrorism Act and Project Bioshield. First, Congress created an agenda to develop a critical aspect of the nation's defense against bioterrorism. As is often heard: it is not a matter of if, but when, another terrorist will strike. In the event of bioterrorist attacks, a national stockpile of countermeasures that will treat or vaccinate potential victims could prevent or at least contain a serious public health crisis. Thus, setting the goal of creating a national stockpile, as Congress did with the Bioterrorism Act of 2002, is imperative. Congress went an important second step with Project Bioshield: recognizing that the creation of an adequate stockpile depends on the availability of countermeasures not yet developed, Congress passed Project Bioshield to put into place a framework conducive to the development of necessary countermeasures. As will be discussed below, serious weaknesses within the legislation currently prevent the actualization of the laudable goals of developing countermeasures and creating an adequate national stockpile, but nonetheless, setting the proper agenda represents an important strength of the Bioterrorism Act and Project Bioshield that must not be overlooked.

Second, the public-private partnership that emerges from Project Bioshield is arguably critical to the success of Congress's goals of developing and stocking countermeasures that will meet the needs of the nation in the event of bioterrorist attacks. Congress's attempt to foster a mutually beneficial relationship with the private sector potentially bodes well for the future of the stockpile. In a sense, Congress flipped the normal relationship between the government and the private sector upside down: normally the FDA fulfills a "gate-keeper" role in protecting the public from potentially dangerous medical drugs and products. This role led

to a conservative FDA that engaged in time-consuming approval processes for products.⁵⁴ With the passage of both the Bioterrorism Act and Project Bioshield, the government now takes an active role in soliciting private sector activity⁵⁵ and expedites the approval process for critical countermeasures.⁵⁶ Arguably, the FDA's conservatism with respect to countermeasure approvals has (or will) morphed into activism.⁵⁷ While one might argue that this potentially creates some conflicts of interest that could compromise safety, nevertheless, this private-public relationship articulated by Congress represents a willingness to pursue new and flexible means of achieving the twin goals of developing and stocking critical bioterrorist countermeasures. Hopefully, Congress can make the appropriate adjustments in the future where obvious complications arise that compromise safety, while remaining committed to a flexible approach that pursues cooperation with the private sector towards a common goal rather than antagonism and excessive conservatism.

The third strength of these Acts lies is simple: Congress committed \$5.6 billion dollars to the development and procurement of countermeasures for the stockpile over the next 10 years. To be sure, criticisms exist regarding the amount of funding (not enough)⁵⁸ and the particular use of the \$5.6 billion dollars,⁵⁹ but the fact still stands that Congress committed a substantial amount of money towards the development and procurement of countermeasures. To the extent that allocation of funds provides the best indication that Congress seriously prioritizes a particular project, this funding speaks volumes about the seriousness of Congress's

⁵⁴See James T. O'Reilly, *Bombing Bureaucratic Complacency: Effects of Counter-Terrorism Pressures upon Medical Product approvals*, 60 N.Y.U. ANN. SURV. AM. L. 329, 338 (2004)(looking at changed incentives for manufacturers in wake of anthrax scare, and how bio-terrorism threats changing FDA bureaucratic norms).

⁵⁵Under Project Bioshield, the HHS Secretary can identify a necessary countermeasure not yet developed, submit a proposal to develop this countermeasure for approval by the President, and then solicit development of this countermeasure by the private sector. See *supra* text accompanying notes 31-32.

⁵⁶See *supra* text accompanying notes 24-25, 36-37.

⁵⁷See *supra* note 55, James T. O'Reilly, *Bombing Bureaucratic Complacency: Effects of Counter-Terrorism Pressures upon Medical Product approvals*, at 338.

⁵⁸With some estimates of the funds necessary to create an adequate shield against bioterrorism set at \$50 billion, some could argue the \$5.6 billion funded in Project Bioshield is insufficient. See *Drug Problem: Biodefense*, ECONOMIST, April 24, 2004 (By most estimates, building the necessary biodefense, which includes 100 new diagnostics, vaccines and treatments, will take at least 5-10 years and \$50 billion).

⁵⁹See *One Year Later: Evaluating the Effectiveness of Project BioShield: A Hearing before the House Committee on Government Reform*, 109th Cong. (July 14, 2005)(comments by US Rep Henry Waxman (D-CA)(arguing that BioShield's limited funds should not be used to buy outdated anthrax vaccines, but to develop next generation ones; funds to buy the necessary older anthrax vaccines should come from general public health funds).

(and the President's) commitment towards these developing and stocking critical bioterrorist countermeasures. It should be remembered that the Bioterrorism Act did not include such significant funding; Project Bioshield thus represents a deepening commitment of Congress and a step in the right direction.

2. Weaknesses

One can state simply the primary weakness of the Bioterrorist Act and Project Bioshield: they have failed to achieve their stated purposes. The private sector is not jumping on board to develop critical countermeasures as intended by Project Bioshield. In addition, even if the stockpile contained adequate supplies, state and local governments are currently unprepared to receive and deliver necessary vaccines or other countermeasures in the event of a real emergency triggered by bioterrorism.⁶⁰

While Congress and other relevant authorities must focus on both problems, this section will not analyze the state and local governments' general lack of capacity to distribute stockpile contents. Much has already been written on the topic⁶¹ and it arguably represents an independent, albeit related, issue. Instead, this section will analyze the other major weakness of the current legislation: the private sector is not jumping on board to develop critical countermeasures that the government can then procure for the national stockpile.

⁶⁰See e.g. Mimi Hall, *Cities fret over how to quickly deliver vaccines*, USA TODAY, p 3A Aug. 1, 2005 (in 2004, HHS devoted \$27 million to 21-city program called the Cities Readiness Initiative because currently, the public health system (state and local) constitutes "one of the weakest links in our national defense"); Jeff Nesmith, *U.S. gets poor grade for terror prep*, The Atlanta Journal Constitution, P 5A, December 7, 2005 (Panel of 20 public health experts conclude that only 7 states are qualified to receive deliveries from the national strategic stockpile— Texas, Florida, Virginia, Missouri, Louisiana, Illinois and Delaware). Cf. *The Federal Response to Hurricane Katrina: Lessons Learned*, February 2006, available at <http://www.whitehouse.gov/reports/katrina-lessons-learned.pdf> (last visited March 1, 2006) ("During the Federal response to Katrina, four critical flaws in our national preparedness became evident: Our processes for unified management of the national response; command and control structures within the Federal government; knowledge of our preparedness plans; and regional planning and coordination" at p. 52)

⁶¹See *id.*; see also Lori L. Buchsbaum, *The U.S. Public Health Response to Bioterrorism: Need for a Stronger Legislative Approach*, 7 MICH. ST. J. MED. & LAW 1 (2002) (to avoid worst case scenario, the nation must strengthen current state and federal public health responses to bioterrorism); *Furthering Public Health Security: Project BioShield: Hearing before the Subcommittee on Health, House Energy and Commerce Committee and the Subcommittee on Emergency Preparedness and Response, House Select Homeland Security Committee*, 108th Cong. (Mar. 27, 2003).

Multiple explanations exist for the private sector's lack of enthusiasm. The experience of Hollis-Eden Pharmaceuticals, a biotechnology firm seeking a government contract under Project Bioshield⁶² for an anti-radiation drug, illustrates some of these explanations. Hollis-Eden spent \$100 million to develop its drug⁶³—Nuemune—as a medical countermeasure against radiological weapons of mass destruction.⁶⁴ Hollis-Eden and market watchers speculated that the government, under Project Bioshield, could buy as many as 10 million doses of Nuemune at \$50 each, for a total contract worth \$500 million.⁶⁵ However, the government instead issued a request for proposal (RFP) to acquire enough doses to treat only 100,000 civilian casualties.⁶⁶ With its hope for a lucrative government contract gone and its stock plunging, Hollis-Eden criticized the government's actions as sending a very negative signal to private companies interested in pursuing development of countermeasures under Project Bioshield.⁶⁷

Hollis-Eden's experience demonstrates two key weaknesses of the current stockpile and development of countermeasures legislation. First, Project Bioshield fails to create a guaranteed market for newly developing countermeasures and vaccines—without a guaranteed market, companies such as Hollis-Eden may quickly learn that the risk that a market will never materialize for their product (governments represent the only customer for these products) greatly outweighs any potential profit. Companies will not risk significant sunk costs but will instead continue to invest in drugs that treat chronic conditions such as hypertension, cancer

⁶²Project Bioshield is not limited to development of countermeasures to bioterrorism. It encompasses countermeasures to chemical, biological, radiological, or nuclear attacks. See Michelle Meadows, *Project Bioshield: Protecting Americans from Terrorism*, FDA CONSUMER MAGAZINE, Nov-Dec 2004, available at http://www.fda.gov/fdac/features/2004/604_terror.html (last visited on March 1, 2006).

⁶³Mark Kaufman, *New Worries on BioShield Effort; Request for Medicines Called Too Small to Support Firms*, WASHINGTON POST, p A21 (Oct 5, 2005).

⁶⁴Even though this is an anti-radiation drug and not a bioterrorism countermeasure, the experience is instructive because makers of bioterrorism-related vaccines and countermeasures face the same problems.

⁶⁵Penni Crabtree, *Hollis-Eden shares fall on limited drug order: Maker of anti-radiation treatment criticizes plan*, SAN DIEGO UNION TRIBUNE (Oct. 1, 2005).

⁶⁶*Id.*

⁶⁷See Mark Kaufman, *New Worries on BioShield Effort: Request for Medicines Called Too Small to Support Firms*, *supra* note 64.

and heart disease that promise guaranteed markets and profits.⁶⁸ Second, a lack of transparency in the government procurement process means that companies must invest in the development of products without any concrete guidance and advice from the government; this hinders companies from making efficient and informed choices about R&D. Pharmaceutical companies have testified before Congress seeking correction of both flaws.⁶⁹

In addition to weaknesses relating to unsatisfactory government actions, current legislation fails to spur private companies into developing critical countermeasures because Congress fails to fund development of a product from proof of concept until procurement into the national strategic stockpile. Thus, pharmaceutical companies speak of a “Valley of Death” that refers to the funding gap between the discovery of a promising new product and the manufacturing, human safety and animal efficacy studies.⁷⁰ In addition, manufacturers of products criticize the government for failing to assist in manufacturing process. They seek funding to maintain a “warm base”—to keep a plant ready to begin manufacturing of a product (i.e. smallpox vaccine) at a moment’s notice⁷¹—and to assist in the general upkeep of a plant to ensure it satisfies all regulatory requirements. As the flu vaccine shortage in 2004 demonstrated, only one or two manufacturers produce a

⁶⁸ *One Year Later: Evaluating the Effectiveness of Project BioShield: A Hearing before the House Committee on Government Reform*, 109th Cong. (July 14, 2005) (Statement of Gerald L. Epstein Senior Fellow, Science and Security Center for Strategic and International Studies)(“These conditions provide large and continuing markets, whereas most infectious diseases occur only sporadically, particularly in the developed world markets that can readily afford pharmaceutical products. The required course of anti- infective treatment lasts only a week or two - and if successful it clears up the problem, eliminating the need for further business. Pharmaceutical manufacturers would rather devote their resources to drugs with larger and more lucrative markets – and they would be punished by their investors if they didn’t”).

⁶⁹ *Linking Bioterrorism Threats and Countermeasure Procurement before the Committee on House Homeland Security Subcommittee on Emergency Preparedness, Science, and Technology*, 109th Cong. (July 12, 2005)(Statement of David P. Wright President & CEO, PharmAthene, Inc)(discussing the need for more transparent government decisions regarding future contracts for specific products); *Hearing on Bioshield Act of 2003 before the House Government Reform Committee* (April 4, 2003)(Prepared statement of McKenna Long, Representative of Aventis Pasteur)(discussing the need for Congress to create guaranteed markets for products and for returning the costs of capital and return on equity in the event of termination of a government contract to buy products).

⁷⁰ *Medical Countermeasures in Bioshield: Hearing before Senate Health, Education, Labor and Pensions Subcommittee on Public Health*, June 9, 2005 (Statement of David P. Wright President and Chief Executive Officer, PharmAthene)(comparing the Valley of Death gap in Project Bioshield with the DOD’s “Milestone B,” which funds the Valley of Death gap)

⁷¹ Ross Kerber, *Vaccine Makers Seek Funds to Stay Ready: They ask Government for help to keep plants primed in case of bioterror attacks*, BOSTON GLOBE, C1, May 6, 2005 (Acambis Inc. has delivered 182.5 million doses of smallpox vaccine to the stockpile and seeks funding to maintain a “warm base”).

given vaccine⁷² and any problems with a manufacturing plant (the contamination of a British plant caused the flu vaccine shortage in 2004) can cause a severe vaccine shortage.⁷³ Thus, Project Bioshield's failure to create an all-encompassing vision of the funding process constitutes a serious weakness.

Finally, and most notably, the Bioterrorism Act and Project Bioshield fail to offer both liability protections for companies and compensation for adversely affected patients. This creates two problems. First, companies will not invest in such products as vaccines and countermeasures to bioterrorism carry serious unavoidable risks. This explains one major reason Project Bioshield has failed to spur private companies to invest in priority countermeasures and vaccines—the benefits do not outweigh the almost certain risks.⁷⁴ Second, citizens will not avail themselves to available vaccines, such as smallpox, if a compensation scheme is not in place. The smallpox vaccine program initiated by President Bush⁷⁵ is instructive: roughly 40,000 received a smallpox vaccine originally intended for 500,000 (less than 10 percent).⁷⁶ Without any promise of compensation and restoration to pre-injury position, health care providers refused to receive the vaccination. Project Bioshield's failure to provide liability for companies and compensation for victims has received perhaps the most public attention; indeed, legislation designed to fix these flaws is pending in Congress.⁷⁷

In sum, three main weaknesses of the stockpile related provisions of Bioterrorism Act and Project Bioshield stand out: the government's inefficient handling of the procurement process (lack of transparency and lack of guaranteed markets); the government's overly narrow vision of the funding process (ignores "Valley of

⁷²See Gail H. Javitt, *Drugs and Vaccines for the Common Defense: Refining FDA Regulation to Promote the Availability of Products to Counter Biological Attacks*, 19 J. CONTEMP. HEALTH L. & POL'Y 37, 92-93 (2002)(only 1 manufacturer for many vaccines; vaccines compromise only 1-2% of global sales).

⁷³Jennifer Lee, *Kerry Says U.S. Should Have Prepared for Flu Shot Shortage*, NEW YORK TIMES, p 38, Oct 10, 2004)

⁷⁴Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7 at 9 (Congress must protect manufacturers, sellers, and distributors of the vaccine from liability and also compensate those injured by the vaccination).

⁷⁵*Bush orders smallpox vaccine for military, for himself*, CNN, Jan 30, 2004, available at <http://archives.cnn.com/2002/HEALTH/12/13/bush.smallpox/> (last visited on March 1, 2006).

⁷⁶*Supra* note 75 Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7 at 8-9.

⁷⁷See e.g. S. 975, 109th Cong. (2005); S. 3, 109th Cong. (2005); S. 666, 109th Cong. (2005)

Death” and manufacturing issues); and Congress’s failure to provide liability protections and victim compensation.

C.

Recommendations for Future Governmental Action

1. Liability and Compensation Provisions

Serious development of vaccines and countermeasures to bioterrorism will only occur if Congress extends liability protections to companies investing in such products. Insurance is unlikely to cover companies that develop and sell vaccines and countermeasures to bioterrorism, given the unavoidable risk such products entail. With high returns assured in safer, more lucrative products, rational companies would not invest in countermeasures and vaccines. Even though generic and name brand companies clash on many aspects of “Bioshield II,” both agree that liability protection for companies is critical.⁷⁸ Currently, the many competing Bioshield II legislation pending in Congress include liability protections for companies.⁷⁹

Compensation for persons injured from vaccines or countermeasures goes hand-in-hand with liability protections. Government should not leave victims without any recourse for injuries suffered, as potentially could happen if liability protections were extended without compensation provisions. The small pox vaccination fiasco discussed above proves instructive.⁸⁰ Thus, Bioshield II legislation should extend compensation similar to the National Childhood Vaccine Injury Fund.⁸¹

⁷⁸Ted Agres, *Coaxing Pharma out of the Gate*, DRUG DISCOVERY AND DEVELOPMENT, P 14, June 1, 2005.

⁷⁹See *supra* note 77.

⁸⁰See text accompanying *supra* notes 75-76.

⁸¹*Supra* note 75 Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government’s Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL’Y 7 at 31-35 (arguing that costs are manageable: the government has awarded \$ 629 million for 1,249 awards in NCVIA claims and attorneys’ fees for childhood vaccine injuries since 1990 and nearly \$ 7 billion for 5,000 families from the by Sept 11th fund).

2. Government articulation of concrete goals: transparency in procurement

As the above Hollis-Eden story illustrated, government must articulate clearly and early what countermeasures and vaccines the government seeks, and in what quantities. If not, and if more Hollis-Eden stories abound, companies will shy away from an uncertain government market. Congress has arguably done its part in articulating clearly the goals of creating a national stockpile and providing the necessary funding to develop countermeasures; it is now up to the HHS and other relevant agencies to contribute to these ends by creating a transparent procurement process that will provide information and insights to the private sector necessary to structure appropriate investments in vaccines and countermeasures to bioterrorism. Numerous representatives of pharmaceutical companies have begged for such transparency before Congress.⁸²

3. Be creative in using incentives to encourage investment in the development of stockpile contents

Two bills currently pending in Congress typify the general strategy Congress seems prepared to take in confronting the reality that companies are not investing in the development of much needed stockpile contents: the bills assume that Congress must bribe the private sector into developing countermeasures and vaccines with tax breaks and patent extensions. Thus, Senators Hatch and Lieberman’s “Bioshield II”⁸³ bill offers a two-year “wildcard” extension on an unrelated patent to the company that develops necessary countermeasures or vaccines.⁸⁴ Similarly, another Senate bill offers an additional two-year market exclusivity for any

⁸²See e.g., *Linking Bioterrorism Threats and Countermeasure Procurement before the Committee on House Homeland Security Subcommittee on Emergency Preparedness, Science, and Technology*, 109th Cong. (July 12, 2005)(Statement of David P. Wright President & CEO, PharmAthene, Inc)(government must identify its needs early enough for companies to make informed decisions).

⁸³The bills discussed are not actually titled “Bioshield II” but will be a shorthand characterization because nevertheless these bills attempt to fill the gaps left by the Project Bioshield of 2004.

⁸⁴Ted Agres, *Coaxing Pharma out of the Gate*, DRUG DISCOVERY AND DEVELOPMENT, P 14, June 1, 2005 (Hatch and Lieberman, *Biological, Chemical, and Radiological Weapons Countermeasures Research Act* (S. 666), includes tax credits, intellectual property incentives, and liability protections in addition to the wildcard exception).

countermeasure developed, as a reward to the company who undertakes such investment.⁸⁵

Such attempts to bribe the private sector with patent extensions or similar financial incentives do not necessarily represent the best strategy. It would be difficult for Congress to determine the optimal amount of financial incentives necessary to induce companies to develop these countermeasures in the most efficient manner. If Congress offers too few financial incentives, companies still will not bite and much time and effort has been wasted by Congress. Indeed, it seems questionable at best if Congress could ever offer enough incentives to convince pharmaceutical companies to forgo investment in potential blockbusters that treat chronic conditions and instead invest in vaccines and countermeasures that may be used for only a short period of time, and that may be bought only by one customer—the U.S. government. If Congress could provide sufficient bribes, one wonders whether such investment is the best use of the government’s limited resources. Moreover, if Congress offers too many incentives, such as overly generous patent extensions, competition could actually be inhibited to the detriment of the contents critical for the National Strategic Stockpile.⁸⁶ Instead of relying on a strategy of bribing, and accepting its attendant risks and uncertainties, the government should creatively expand its vision of development and procurement of products for the national stockpile. The government should consider two alternative strategies in particular: first, bring new players into the research and development picture beyond the drug industry, namely, other countries who can expand the market available for these products, philanthropic foundations such as the Bill and Melinda Gates foundation, and universities who would be happy to accept continued funding for niche research centers. Second, the government should leverage its resources against an uncooperative private market to force the

⁸⁵Senators Gregg, Frist et al, *Protecting America in the War on Terror Act of 2005* (S.3).

⁸⁶See e.g. Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U. J. SCI. & TECH. L. 1 (2005)(arguing that proper incentives to develop strong biopharmaceutical products lie in curbing and limiting doctrine of equivalents in patent system in predictable manner—not being overly generous towards patentees which will stifle innovation and competition).

private sector to come up with its own creative strategies to balance the need for critical countermeasures to bioterrorism with the need to turn a profit. If the pharmaceutical industry feels threatened by government, it may take the initiative to create solutions on its own, as has the food and cosmetic industry in the past.

Strategy #1: Bringing other players to the table: Bill and Melinda Gates have donated \$31 billion to their foundation, which primarily addresses global health problems.⁸⁷ The funds from Gates' foundation are used to "overcome the market failure afflicting poor consumers of health care" and to supply much needed medicines to poor consumers.⁸⁸ The Gates are not alone: his example arguably has set off a firestorm of philanthropic giving⁸⁹ among the world's 691 billionaires.⁹⁰ Bringing philanthropists to the table could serve two purposes: first, philanthropic funds can be used to fund the development of vaccines and countermeasures. Government would not have to worry about calibrating the proper amount of incentives in bribing pharmaceutical companies, as the philanthropic organizations could fund and financially reward dedicated scientists devoted to the cause of developing critical vaccines and countermeasures. Alternately, philanthropic funds could be used to finance any incentives necessary to encourage the private sector rather than government funds. Either option serves the government effectively in ensuring the development of products crucial to the National Stockpile. Given that philanthropists generally use their foundations for much needed social causes, publicity and national gratitude that would accompany the development and procurement of contents for the Strategic Stockpile could be a strong selling point.

Beyond philanthropists, government should generally expand the market for critical countermeasures and vaccines by cooperating with other countries towards a common goal. If all NATO allies provided a guaranteed market for vaccines and critical countermeasures to bioterrorism, it may offer a solution to the reality that pharmaceutical companies are hesitant to invest in products with uncertain and non-guaranteed mar-

⁸⁷ *The Business of Giving*, THE ECONOMIST, Survey p 3, February 25, 2006.

⁸⁸ *The Birth of philanthrocapitalism*, THE ECONOMIST, Survey p 10, February 25, 2006.

⁸⁹ *To have and not to hold: The rise of the new philanthropist*, THE ECONOMIST, Survey p 5, February 25, 2006.

⁹⁰ *The Business of Giving*, THE ECONOMIST, Survey p 3, February 25, 2006.

kets. A comparison with bird flu vaccines seems apt—with the whole world in potential need of such vaccines, companies such as Solvay that produce such vaccines, should make good profits from its global market.⁹¹ Coordination of governments towards multi-nation purchasing from one company could be a laudable goal of Congress or the appropriate federal agency.

Finally, funding of academic centers devoted to the development of vaccines and countermeasures to bioterrorism that can be procured for the National Stockpile presents a potentially less costly means to secure development without bankrupting the treasury. The National Institute of Allergy and Infectious Diseases (NIAID) has already begun funding of “centers of regional excellence”—academic centers designed to focus on the application of scientific knowledge through the development of priority countermeasures to bioterrorism.⁹² Harvard Medical School received one such award.⁹³ The publicity such centers would generate from the development of countermeasures or vaccines, in addition to the guaranteed government funding for ongoing research, would provide sufficient reward and incentives for academic centers to pursue the research the private sector currently refuses to pursue. The government should thus consider expanding such initiatives *and* deepening the cooperation between such centers. That is, government could condition its grants on the mutual cooperation among such centers so that academic infighting does not unnecessarily deter the development of critical countermeasures and vaccines.

Strategy #2: Create incentives for private industry to create its own workable solutions: In truth, it seems unlikely that the promise of profit made off critical countermeasures and vaccines is sufficient to cause companies to invest the necessary amounts to develop such products. The government should use its leverage of carrots and sticks in a more creative way to force the industry to create its own solutions. Just as the

⁹¹See Andrew Jack, *Europe Set to Buy up supplies of Flu Vaccines*, FINANCIAL TIMES, March 2, 2006, available at <http://news.ft.com/cms/s/077f389c-aa1e-11da-96ea-0000779e2340,s01=1.html> (last visited on March 4, 2006).

⁹²Alison Motluk, *Big spending on biodefence has given research into new vaccines and antivirals a massive shot in the arm*, NEW SCIENTIST, P 56, Oct. 23, 2004.)

⁹³*Id.*

food and cosmetic industries demonstrated that self-regulation is possible when the threat of government intervention looms large,⁹⁴ so, too, might the drug industry determine a means to create its own solution to the need for the development of stockpile products. Using its soft power of carrots, government could promise pharmaceutical a powerful publicity campaign on its behalf if the industry would create a common board or pool of pro-bono scientists who would devote themselves to develop these critical countermeasures and products. If the burden of such pro-bono work were spread around among companies, the costs could be affordable. The public's cynical view of pharmaceutical companies might quickly alter in the face of such positive publicity, and certain brand names associated with the pro-bono development of products for the national defense could see a definite boost in consumer loyalty.

If it is too optimistic to hope for carrots to produce such outcomes, the government could leverage its sticks against the industry. Instead of providing tax incentives to pharmaceutical companies as a form of bribery, government could promise tax increases, shorter patent lives or anything else to essentially scare the pharmaceutical industry into designing a method to stave off such government actions and to create a pro-bono pool of scientists or funds to develop the necessary products. Again, if pharmaceutical companies worked together on such an endeavor, the shared burden could create an affordable solution to the current reality that no company is developing the necessary products. The government could justify its threats based on the seriousness of the need to develop critical countermeasures to bioterrorism—if individual companies will not create the products, government will tax companies to raise the necessary funds to pay other scientists to develop the countermeasures.

While the cultivation of an industry norm that certain products require a pro-bono commitment (similar to

⁹⁴These industries self-regulate the approval of product ingredients through the creation of independent review boards such as the Cosmetic Ingredient Review Panel, and the review organizations in the food industry such as the Food and Extract Manufacturing Association (FEMA). Incentives in large part arise from a desire to keep government from further regulating the industry. See, e.g., Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Cosmetics*, in *COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT* (Ed. by Norman Estrin and James Akerson)(2000), p 1-41 at 29 (no industry in U.S. more successful at self-regulation than cosmetic industry).

the pro-bono hours worked by lawyers or doctors) seems a very good solution, it is only offered as one of many solutions the industry could create. The means is less important than the outcome—the development of critical products that government can procure for the National Strategic Stockpile. If the proper carrots (not pure financial bribery) or sticks are utilized, the government could make the best use of its limited uses by securing its desired outcome in the most cost-efficient manner.

Part IV. Conclusion

The National Strategic Stockpile represents an important and laudable Congressional goal. Unfortunately, the Stockpile’s success depends on the procurement of countermeasures and vaccines not yet created developed. In drafting legislation to ensure the development of these critical products, the government should take a creative approach to designing incentives and strategies. Rather than rely solely on the same-old, same-old methods of bribery, the government should include non-traditional actors such as philanthropists, foreign governments, and academic centers in its plans. Moreover, the government should pander less to industry and instead leverage its available sticks and carrots to compel the drug industry to accept the responsibility of developing vaccines and countermeasures for the common good—rather than rely on government to write the terms, government should assist industry in creating the necessary conditions for the private sector to construct its own solutions to this need. In this way, the government can use its limited resources in the most effective and cost-efficient manner.

Luckily, no bioterrorist attack has yet created a serious public health crisis. However, we cannot afford to continually rely on luck, but must instead take immediate steps to proactively and intelligently ensure the build-up of a strong and robust Strategic National Stockpile.